SUMMARY OF EXPRESS TERMS

This rule requires that the use of controlled substances in the euthanasia of animals is done in a humane manner according to nationally accredited standards. These amendments include clarification that the incorporated societies eligible to obtain controlled substances for euthanasia are duly incorporated societies for the prevention of cruelty to animals, duly incorporated humane societies, or duly incorporated animal protective associations, which maintain an active Board of Directors, and have facilities for the care and eventual disposition of animals.

The proposed regulations also clarify that euthanasia technicians are required to complete a minimum of two hours of continuing education every two years. To be consistent with Correction Law Article 23-A, the amendment requires the use of a balancing test when reviewing application forms for euthanasia technician applicants who have criminal convictions.

Further, the amendments will also ensure that no pentobarbital will make its way into the food supply by requiring that animals euthanized with pentobarbital are not rendered as food.

Pursuant to the authority vested in the Commissioner of Health by section 3305 of the Public Health Law, section 80.134 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register for a permanent regulation, to read as follows:

80.134 Authorization for the purchase, possession and dispensing of ketamine hydrochloride only to anesthetize animals for euthanasia, and of sodium pentobarbital to euthanize animals.

(a) Except where different meanings are specified expressly, the terms in this section shall have the following meanings:

(1) An incorporated society [for the prevention of cruelty to animals (society)] shall include [any] duly incorporated [humane society or society] societies for the prevention of cruelty to animals, duly incorporated humane societies, or duly incorporated animal protective associations, maintaining a Board of Directors consisting of three or more members who are involved and knowledgeable of the activities of the corporation, having facilities for the care and eventual disposition of animals, within the State, that is exempt from taxes pursuant to paragraph (3) of subsection (c) of section 501 of the federal Internal Revenue Code, 26 U.S.C. 501, or any subsequent corresponding sections of the federal Internal Revenue Code, as from time to time amended.

(2) Municipal animal control facility (facility) shall include any pound or shelter maintained by or under contract or agreement with any county, city, town or village within the State.

(3) Solution shall mean:

(i) a premixed solution of sodium pentobarbital, manufactured only and specifically for the euthanasia of animals, which contains such other ingredients as to place such solution within schedule III of the Controlled Substances Act (article 33, Public Health Law);

(ii) schedule II sodium pentobarbital; and

(iii) ketamine hydrochloride only for the purpose of anesthetizing animals for euthanasia.

(4) An agent is a person or persons other than a licensed veterinarian appointed by the incorporated society or municipal animal control facility, and duly registered with the department, authorized to purchase, possess and dispense (i) ketamine hydrochloride only to anesthetize animals for euthanasia, and (ii) sodium pentobarbital to euthanize animals.

(5) A [registered individual] euthanasia technician is a person certified and registered pursuant to subdivision (f) of this section.

(b) No incorporated society, facility or its agent shall purchase, possess, dispense or cause to be administered, a controlled substance within this State without first registering with the department.

(c) [A] An incorporated society or facility and its agents shall also [register] maintain an active registration with the Federal Drug Enforcement Administration (DEA) in the controlled substance schedule provided for under this Part.

(d) [Any] An incorporated society or facility [may] shall register an agent to purchase, possess and dispense a controlled substance, by application to the department.

(1) The department shall issue such registration unless the commissioner finds that the application should be denied by reason of false statements in the application, conviction of a felony relating to controlled substances, suspension, revocation or denial of the applicant's Federal DEA registration, failure to provide adequate safeguards against diversion of the solution, or other good and sufficient reason such as conviction for a violent felony or a felony related to theft, an administrative determination that article 33 of the Public Health Law or provisions of this Part were violated, conviction for a misdemeanor relating to controlled substances, or any conviction under the Agriculture and Markets Law relating to the treatment of animals.

(2) Such registration shall be valid for a period of three years from the date of issuance and may be suspended or revoked upon a finding by the commissioner that the incorporated society, facility, agent or certified personnel have violated the provisions of this section, or any other requirement of this Part or article 33 or any other State law or regulation relating to the proper care of animals by incorporated societies or facilities. Applications for renewal of such registration shall be filed with the department prior to the expiration thereof. An incorporated society or facility that fails to submit a timely renewal application may be subject to sanctions, including denial of new registration or civil penalties as determined by the department.

(3) [Any] An incorporated society or facility registering an agent shall immediately notify the department of any change in the employment or contractual relationship with the designated agent.

(4) Such registration shall be valid only at the registered location.

(e) (1) [Registered agents or] Incorporated societies or facilities may dispense solution for the euthanasia of animals only to [registered individuals] euthanasia technicians certified by the department to administer such a solution; or to a licensed [and properly registered] veterinarian and only for on-premises use.

(2) Solution may be dispensed for use off the premises only where the animal to be euthanized is injured or transport of such animal to the society or facility is not [practical] appropriate.

(3) Euthanasia technicians or licensed veterinarians may administer solution only for the humane euthanasia of animals using techniques deemed "acceptable" by the American Veterinary Medical Association. No animal shall be left unattended between the time that the euthanasia procedure begins and the time when death is confirmed.

(f) Registration and certification of [individuals] euthanasia technicians to administer solution for euthanasia of animals.

(1) No person other than a licensed veterinarian shall receive a controlled substance from a duly authorized agent of a society or facility to euthanize animals unless the person is certified [and registered with] as a euthanasia technician by the department.

(2) To obtain a certification and registration from the department in order to administer a solution to euthanize animals, the applicant must:

(i) be [21] 18 years of age or older;

(ii) hold a bachelor or associate degree in animal health sciences or related field; and

(iii) obtain a written certification from two licensed veterinarians or one licensed veterinarian and one licensed [animal health] veterinary technician in which the

veterinarians or technicians state that they have observed the proficient use, by the applicant, of injections for the euthanasia of animals.

(3) Any person who meets the minimum qualifications stated in subparagraphs 2 (i) and (iii) of this subdivision, but who lacks the require bachelor or associate degrees, may obtain certification and registration from the department if such person has two years' experience in animal care including euthanasia of dogs and cats.

(4) The department shall issue such registration and certification unless the commissioner finds that the application should be denied by reason of false statements in the application, the applicant's conviction of a felony relating to controlled substances unless the applicant is eligible after a balancing of the factors set out in article 23-A of the Correction Law. In accordance with that article, no application for registration shall be denied by reason of the applicant having been previously convicted of one or more criminal offenses unless:

(i) there is a direct relationship between one or more of the previous criminal offenses and duties required of the registration; or

(ii) registering the applicant would involve an unreasonable risk to property or the safety or welfare of a specific individual or the general public.

In determining these questions, the department will look at all factors listed under New York State Correction Law section 753 or for other good and sufficient reason.

(5) Such registration and certification shall be valid for a period of three years from the date of issuance and may be suspended or revoked upon a finding by the commissioner that the registered individual has violated the provisions of this Part, article 33 or any other State

law or regulation relating to the proper care of animals, or is not competent to administer solution in the euthanasia of animals by injection.

(g) Renewal of euthanasia technician registrations. Registrations issued under this section shall be renewed by the department upon receipt of a completed renewal application which includes proof of attendance of a minimum of two hours continuing education at a department[-sponsored or] approved course in the safe and effective use of a solution for the purposes of euthanasia of an animal and/or in the treatment and care [in] of the euthanasia of animals.

(h) Safeguarding of solution. Agents shall safeguard the solution in compliance with the standards for safeguarding controlled substances set out in section 80.6(a) and (b) of this Part.

(i) Minimum security standards for a society, facility and its agents.

(1) The [solution] stocks of controlled substances must be stocked in a securely locked cabinet of substantial construction. The cabinet shall be stationary and made of steel or other approved metal and of sufficient size to store the stock of solution. The cabinet shall have inner and outer doors, shall have key-locked doors with separate keys; spring locks or combination dial locks are not acceptable. For new construction, cabinets shall be made of steel or other approved metal.

(2) The cabinet shall be limited to the storage of the solution, needles and syringes and solution records.

(j) Recordkeeping requirements.

(1) Agents shall keep records of all solution purchased, dispensed and administered.

(2) All purchase records, including a copy of the invoice, shall be kept in a separate file and filed by date received.

(3) A separate record of solution activities and transactions in the form of a running inventory shall be maintained and include the following:

(i) the name of the drug (by brand name);

(ii) the name of the manufacturer, lot number, NDC number;

(iii) the strength of the drug in milligrams (mg) per milliliter (ml);

(iv) the total amount of drug received in milliliters;

(v) the name, address and DEA registration number of the supplier of the drug;

(vi) the date the solution was received;

(vii) the signature of the person receiving the solution;

(viii) the date of any transaction or activity, the amount of the solution dispensed at each dispensing;

(ix) the signature of the agent who dispensed the solution;

(x) the signature of the [registered individual] euthanasia technician or licensed veterinarian administering the solution; [and]

(xi) the total amount of solution not administered that was wasted or destroyed in milliliters (ml); and

(xii) the remaining amount of drug on hand in milliliters (ml).

(4) Any unused solution must be returned to the agent for destruction. The agent must record the date, the amount returned, the signatures of the agent and the [registered individual] euthanasia technician or licensed veterinarian returning the drug, and the amount on hand after such transaction.

(5) A separate record shall be maintained of all losses with a brief statement describing the incident and signed by the agent and a witness.

(6)(i) Agents shall cause the [registered individual] euthanasia technician and any contracting practitioner to receive a work card or medical record sheet when dispensing the solution and such record shall be returned to the agent upon completion of each workday.

(ii) The work card or medical report sheet shall contain information to properly identify each animal to whom the solution is administered. For each female with litter, utilize only one record or card.

(iii) The [registered individual] euthanasia technician or the licensed veterinarian euthanizing such animal shall document on such record the date of the administration of the drug, the amount of the drug used in milliliters (ml), the technique used to destroy any unused amount of the drug, and the registered individual's signature.

(7) All records pertaining to the solution shall be kept on the premises of the incorporated society or facility for a period of five years and shall be available readily and produced promptly for inspection by authorized representatives of the commissioner.

(k) Quarterly reports. Within 10 days of the end of each quarter of each year, the society or facility shall submit the department approved form to report to the department signed by an officer or official and the agent and include the following:

(1) the name, address and phone number of the society or facility;

(2) the agent's name, bureau registration number, DEA registration number;

(3) the total amount of solution received from suppliers;

(4) the total amount of solution dispensed to personnel;

(5) the total amount of solution wasted or destroyed;

(6) the total amount of solution returned from personnel;

[(6)] (7) the total amount of solution lost for any reason;

[(7)] (8) the total amount of solution on hand at the end of the quarter;

[(8)] (9) an actual physical inventory count of solution on hand; and

[(9)] (10) the total number of animals euthanized by species.

(l) All agents and registered individuals are under continuing duty to report immediately to the department any loss, theft or diversion of solution from the society or facility. Failure to submit a timely report shall result in a fifty dollar fine. The department may also suspend or revoke registration to agents or incorporated societies for repeated failure to timely submit a quarterly report.

(m) Certification or registration by the department under this section does not authorize the use of medicated darts in a handgun.

(n) [Registered individuals] Euthanasia technicians may administer solution for euthanasia of animals only when in the employ of a registered society or facility and only when solution is obtained from the registered agent of such society or facility.

(o) An agent of a society or facility may also obtain registration as an euthanasia technician [and certification to administer the solution] as defined in [paragraph] subdivision (f)[(2)] of this section. However, the same individual may not act as both the agent dispensing and the [registered individual] euthanasia technician administering in the same facility at the same time.

(p) Agents of an incorporated society or a facility are responsible for the proper safeguarding and handling of hypodermic syringes and needles and must comply with section 80.133(h)-(j) of this Part. All needles and syringes shall be stored in compliance with subdivision (i) of this section.

(q) The agent of a society or facility is not relieved of his responsibilities to detect or correct any diversion or mishandling of any solution by a delegation of responsibility.

(r) Whenever possible, livestock owners should consult with a veterinarian before euthanizing an animal. If it is deemed necessary to euthanize livestock with sodium pentobarbital, such animal may not be rendered into animal or human food supplies.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The Department of Health is directed by Section 3305(1)(d) of the Public Health Law (PHL) to adopt rules and regulations providing for the registration and certification of any individual who, under the direction of the duly authorized and registered agent of an incorporated society for the prevention of cruelty to animals, or municipal animal control facility, uses ketamine hydrochloride to anesthetize animals and/or sodium pentobarbital to euthanize animals. The Department is also given the authority under such section to adopt rules and regulations providing for the safe and efficient use of ketamine hydrochloride and/or sodium pentobarbital by incorporated societies for the prevention of cruelty to animals and animal control facilities.

Further, Section 374 of the Agriculture and Markets Law authorizes the Department of Health to promulgate regulations deemed necessary to ensure the humane euthanasia of animals, including regulations governing the training and certification of certified euthanasia technicians.

Legislative Objectives:

The purpose of PHL Article 33 is to prevent the illegal use of and trade in controlled substances and to provide for the legitimate use of controlled substances in health care, including the humane euthanasia of animals.

Needs and Benefits:

Amendments are necessary to require that euthanasia of animals is done in a humane manner according to nationally accredited standards. These amendments include clarification that that the incorporated societies eligible to obtain controlled substances for euthanasia are duly incorporated societies for the prevention of cruelty to animals, duly incorporated humane

societies, or duly incorporated animal protective associations, which maintain an active Board of Directors, and have facilities for the care and eventual disposition of animals. These proposed amendments reflect circumstances in which unprofessional groups of individuals have been found to not act humanely in their euthanasia activities and who have failed to safeguard controlled substances.

The proposed regulations also clarify that euthanasia technicians are required to complete a minimum of two hours of continuing education every two years. This training ensures that the euthanasia practices used are up to date with the standard of care.

Also, because the federal Food and Drug Administration (FDA) has not established a tolerance for pentobarbital, animal proteins (such as meat and bone meal) and animal fats tested and found to have detectable levels of pentobarbital present cannot be used in food for any animal. This means that animals euthanized with pentobarbital cannot be rendered. The proposed amendments will ensure that no pentobarbital will make its way into the food supply by requiring that animals euthanized with pentobarbital are not rendered as food.

Finally, these amendments will ensure consistency with Correction Law Article 23-A's balancing test that is used when reviewing application forms for euthanasia technician applicants who have criminal convictions.

Costs:

Costs to Regulated Parties:

Euthanasia technicians may incur a nominal cost for completing continuing education every two years.

Costs to State and Local Government:

This regulation does not require the State or local governments to perform any additional tasks; therefore, it is not anticipated to have an adverse fiscal impact on either the State or local governments.

Costs to the Department of Health:

The Department does not anticipate any additional costs.

Paperwork:

The Department does not anticipate any change in required paperwork by the adoption of this amendment.

Duplication:

There are no duplicative or conflicting rules identified.

Alternatives:

An alternative to these regulatory amendments would be to not make any changes and to keep the regulations as written. However, this was not considered a viable option as the changes being made were requested by the Department of Agriculture and Markets and are also necessary to improve the Department of Health's ability to prevent diversion of controlled substances.

Federal Standards:

The proposed regulatory amendment does not exceed any minimum standards of the federal government.

Compliance Schedule:

No additional reporting, recordkeeping, or other affirmative acts are present in this rule change from the current rule. Nonetheless, entities will be permitted 120 days following publication of the Notice of Adoption to develop their internal policies and procedures to assure

compliance with the regulatory changes. Full implementation is expected to occur over a one-year period as entities are able to adopt changes internally. The agency will continue to provide a Notice of Non-Compliance to those entities who have not submitted timely quarterly reports.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

The change in 80.134 will affect twelve (12) animal shelters run by municipalities and thirty-nine (39) organizations under the Society for the Prevention of Cruelty to Animals. Although this proposal will therefore affect small business and local governments that operate these shelters, the Department finds that the proposed regulations are necessary to ensure the health and well-being of New Yorkers. The Department does not anticipate that small businesses and local governments will be unduly burdened by the proposed regulatory changes.

Compliance Requirements:

No additional reporting, recordkeeping, or other affirmative acts are present in this rule change from the current rule.

Professional Services:

Entities will now need to assure that their Controlled Substance Agent is a Department-licensed Euthanasia Technician. Currently, this person is not required to have any specific training to handle controlled substances. This will only affect a small percentage of the entities currently licensed.

Compliance Costs:

No additional capital costs will be incurred for the changes to this rule. A $50.00 fine for failure to submit quarterly reports already required to be submitted, is the only cost change under the proposed rule.

Economic and Technological Feasibility:

No new technological costs will be incurred due to the changes proposed in this rule.

Minimizing Adverse Impact:

The monetary penalty enacted for the entities failure to submit their quarterly reports in a timely manner was set at $50 to reduce the fiscal impact to the entities. It is felt that this is an adequate monetary amount to act as a deterrent to assure regulatory compliance and a higher amount would be too punitive.

Small Business and Local Government Participation:

All stakeholders, including individual facilities operated by small businesses and local governments, are invited to submit public comments in response to the filing of the proposed regulation changes. Additionally, the Department plans to issue a Dear Licensee letter, alerting all currently licensed Euthanasia Facilities, including those operated by small businesses and local governments, of the publication of this regulation and the opportunity to provide public comments.

Cure Period:

Entities will be permitted 120 days following publication of the Notice of Adoption to develop their internal policies and procedures to assure compliance with the regulatory changes. This period crosses over two quarterly reporting periods, which will provide additional time and correspondence between the entities and the Department. Full implementation is expected to occur over a one-year period as entities are able to adopt changes internally. The agency will continue to provide a Notice of Non-Compliance to those entities who have not submitted timely quarterly reports.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not being submitted because the amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no other compliance costs imposed on public or private entities in rural areas as a result of the amendments.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations